

Attorney Docket No.: F3319(C)
Serial No.: 10/678,461
Filed: October 3, 2003
Confirmation No.: 3331

REMARKS

Claims Rejection under 35 USC §112

Claim 1, 4-5, 13-14 and 16 were rejected under 35 USC §112, first paragraph because, according to the Examiner held that the specification, while being enabling for freezing rate, does not reasonably provide enablement for the cooling rate.

The Examiner made the following assertions:

- i) Applicants have not provided sufficient guidance towards the nature of the rate of cooling/freezing. According to the Examiner “freezing rate is defined as a difference between the initial and final temperature divided by the freezing time while “the cooling rate is defined as an instantaneous rate of change of temperature”. The Examiner concluded following a mathematical exposition that “it is not clear whether applicants mean an instantaneous rate of cooling (cooling rate) or freezing rate”.
- ii) The stated limitation of the cooling rate of between 2°C/hr and 320°C/hr does not serve to provide sufficient guidance for one skilled in the art to determine whether applicants refer to cooling rate or freezing rate.
- iii) Applicants have not provided sufficient guidelines concerning the proper protocol for selecting such rate nor has applicants provided working examples as a guidance in this matter and thus it would require undue amount of experimentation for one skilled in the art to produce the recited product employing the recited rate of cooling.

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Regarding item i): The term "cooling rate" has exactly the same meaning as is widely used in industrial process and understood by those skilled in the art to which the invention pertains, namely a Artisans dealing with the cooling, chilling or freezing of foods. Applicants specifically state on page 2, lines 16-18 that the process of the instant invention can be operated at a cooling rate fully compatible with industrial processes.

Applicants specifically disclose on page 3, lines 13-17 that they used a Montford Environment Test Chamber which was programmed to provide a linear gradient from +10°C to -30°C over a period of 16 hours.

Based at least on this disclosure, applicants submit that the meaning of the term "cooling rate" in the context of the present invention would be readily understood by an Artisan to mean: the thermal gradient in time (expressed, for example as °C/min) which a programmable environmental chamber or refrigeration unit applies to the environment (i.e., air) which surrounds its contents (e.g., the fruit) over a specified temperature range or for a specified period of time.

Thus, the cooling rate is neither the instantaneous rate of temperature decline of an object assumed to be a perfect conductor as set forth by the Examiners equations nor an average rate calculated from endpoint temperatures and time.

Regarding item ii): Applicants submits that an artisan reading the specification at page 3, lines 13-17 would readily understand how to achieve any desired cooling rate

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between 2°C/hr and 320°C/hr over a temperature range between 0 °C and -6 °C to -15 °C. The Artisan could at least follow the specification and simply change the cooling program of the programmable environmental chamber to any desired linear thermal gradient between 2°C/hr and 320°C/hr.

Regarding item iii): Applicants teach in claim 1 two results-effective variables which provide criteria for optimizing the cooling rate in the undercooling zone of the environmental chamber for any given fruit within the broad limits of 2°C/hr and 320°C/hr. Namely, the cooling rate should be chosen such that

- the fruit is under-cooled to at least 5°C below the freezing point of the fruit, and
- during under-cooling the cooling rate provides a temperature difference between the surface and core of the fruit which is less than 1.5 °C

Methods to asses both of these variables and reach the recited criteria are well established in the literature (e.g., Asqueth (US 7,169,426) and well know to a person skilled in the art to which the invention pertains. The under-cooling endpoint of at least 5°C below the freezing point of the fruit can be determined through the use of cooling curves where the actual temperature of the fruit is monitored via a thermal couple. The surface/core temperature differential can be measured by placing thermal couples at the surface and the core of the fruit (e.g., 1 mm below the surface as disclosed on page 8, line 1-2) and monitoring the respective temperatures.

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Therefore, armed with the above criteria and the known methods to asses all the criteria, the artisan would simpley conduct a limited series of tests at different thermal gradients (cooling rates) between 2°C/hr and 320°C/hr to establish optimal conditions for the particular fruits or fruit pieces of interest and environmental chambers.

Based on the above arguments applicants submit that the claims 1, 4-5, 13-14 and 16 are fully defined and enabled by the specification to the standard required by 35 USC §112.

Claim 1, 4-5, 13-4 and 16 were rejected under 35 USC 112, second paragraph as being indefinite.

The Examiner asserted that claim 1 was rendered indefinite because of the recitation of frozen fruits which when eaten in the frozen state better retain the flavor and structure of unfrozen fruit.

The Examiner was unclear how frozen fruit have a better flavor and texture than fresh fruit, that it was not clear if frozen fruits produced by the recited method retain flavor and structure that are rated higher when compared to some other products.

Firstly, claim 1 does not recite a frozen fruit which has a better flavor and structure than fresh fruit. The preamble of claim 1 recites a process producing frozen fruits which when eaten frozen better retain the flavor and structure of unfrozen fruit, i.e., the flavor and structure of frozen fruits made by the instant process are closer to fresh fruits than fruits which are frozen, for example, by the conventional blast freezer process.

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Secondly, the flavor and textural properties of frozen fruits prepared by conventional blast freezing (comparative examples 1-3) and by the process recited in claim 1 were evaluated by sensory testing and mechanical assessment. The results are summarized on page 8.

Frozen fruits obtained in examples 1 to 3 (conventional cooling) and 4 to 6 (process of current invention) were eaten frozen at -18°C. Examples 4 to 6 were found to have a much stronger flavour resembling the flavour of original fresh fruits whereas their corresponding frozen fruits in examples 1 to 3 were found to have a milder and 'flatter' taste. This was confirmed when tasting other fruits like bananas and grapes.

The comparison of mechanical data between examples 1 to 3 on the one hand and 4 to 6 on the other hand, showed that, for some fruits, a definite mechanical improvement is achieved through the process according to the invention. More particularly it allows the production of frozen fruits wherein more than 50% by number, preferably above 80% of the fruit bits have a fracture force of less than 0.01kN.

Applicants submit based on these disclosures which are clear and unambiguous, the preamble clearly and definitely describes the metes and bounds of applicants invention to the standard required by 35USC §112, second paragraph.

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Double Patenting

Claim 1, 4-5, 13-14 and 16 were rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of US patent 7,169,462 in view of Yamane et al (EP 0815746)

To facilitate prosecution and without any admission of actual obviousness over the cited combination, applicants have submitted a separate terminal disclaimer and appropriate fee in compliance with 37 CFR 1.321 (c) which applicants assume overcomes the double patenting rejection.

Claims Rejection under 35 USC §103

Claims 1, 3-5 and 13-14 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al (EP0,815,746) in view of Desrosier et al (Fundamentals of Food Freezing) and Jay (Modern Food Microbiology) and other differentials equations cited as evidence as discussed in other Office Actions.

Statement of facts

Yamane is directed to a method of preserving foods or the like in a nonfrozen state in the temperature zone below the freezing point of the food. Abstract and title

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Yamane teaches several embodiments of freezing foods which all require that the food be slowly cooled from the vicinity of the freezing point to below the freezing point at a cooling rate (controlled in essentially the same way as applicants) of 0.01-0.5 C°/hour otherwise, otherwise according to Yamane the invention is not operative. (page 5, lines 6-10)

Yamane teaches that this slow cooling step can be combined with a rapid freezing treatment, in which the food or the like is rapidly frozen to -18°C (Page 9, lines 3-4).

Desrosier disclosure that “great advances have been made in the techniques of freezing fruit rapidly. The present individually quick-frozen (IQF) and cryogenic frozen fruits are superior in quality and stand up better to thawing than the fruits frozen slowly in packages cartons or bulk containers” (p48).

Jay, in “Modern Food Microbiology” (cited by the Examiner), defines on page 325 quick or fast cooling as “a process by which the temperature of foods is lowered to about – 20° C within 30 minutes.” According to Jay this treatment may be achieved through the use of air blasts of frigid air blown across the food being frozen”, e.g., through the use of a blast freezer.

Applicants Arguments

The Examiner has assumed that applicants invention is the combination of a slow cooling rate in the under-cooling region and a rapid cooling rate thereafter. However, the rates which are in fact recited in claim 1 include relatively slower cooling rates and relatively very high cooling rates. The key determinant in selecting the cooling rate is the temperature differential between surface and core of the fruit which must be less than about 1.5°C.

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To qualify as a 103(a) reference "The prior art reference, or combination of references, must teach or suggest all of the claim limitations (MPEP §2143). In addition to providing at least a suggestion of all the claim limitations, both the suggestion and the reasonable expectation of success must be found in the prior art references, not in Appellant's disclosure" (See *In re Vaeck*, 20 U.S.PQ.2d 1438, 947 F.2d 448 (Fed Cir. 1991)

Applicants' limitations on cooling rate based on temperature differential between surface and core of less than 1.5°C is neither taught or suggested by the combination of Yamane, Desrosier and Jay. Consequently, the references can not render applicants' claims obvious under §103(a) at least because the references do not teach or suggest this limitation either explicitly or implicitly.

The Examiner has asserted it would have been obvious to modify the disclosure of Yamane and to vary cooling rates in order to achieve high levels of freshness and quality as disclosed by Yamani. According to the Examiner, one of ordinary skill in the art would have been motivated to do so in order to obtain a superior quality product as taught by Desrosier et al with the cooling rate in the claimed range as evidenced by Jay (lowering of temperatre to -20°C in 30 minutes using a blast freezer).

It is well held that on the issue of obviousness, the combined teaching of the prior art as a whole must be considered. Specifically "It is impermissible within the framework of 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such references fairly suggest to one of ordinary skill in the art" (*EW Corp v. Reliance Universal, Inc* 755

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F.2d at 907 – see also Bausch & Lomb, Inc v. Barnes-Hind/Hydrcurve, Inc 796 F.2d 44, 448-49 (Fed Cir. 1986).

Applicants' respectfully submit that the Examiner has picked and chosen elements from Yamane, Desrosier and Jay that supports an obviousness argument while ignoring key parts of the references which are intrinsically incompatible and which would have discouraged a person of ordinary skill in the art from making the modification which the Examiner has stated a being obvious.

Furthermore, the Examiner has chosen to ignore the comparative examples provided by applicants where essentially the modification suggested by the Examiner was carried out (cooling in the under-cooling region in a blast freezer to -30°C in 1 hour) and found to produce an inferior product relative to the instant process.

To derive applicants claimed invention starting as suggested by the Examiner, a person of ordinary skill in the art would have had to:

- Select from Yamane the concept of combining a “slow cooling” with a “fast cooling” step while ignoring the fact that what Yamane teaches is the combination of an a “super slow cooling” step with a fast cooling step.
- Completely ignore all the teachings of Yamane and use the cooling rate as suggested by Jay of about 40°C/hr (cooling from 0°C to -20°C in 30 minutes) in the under-cooling regime even though this cooling rate is 160 time higher than the highest acceptable rate taught by Yamane.

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Applicants submit that the Artisan would have recognized that such a substitution would have in essence turned the process taught by Yamane into the single stage process taught by Desrosier/Jay because Yamane teaches that under-cooling would not be achieved at cooling rates recited by Jay.

Furthermore, had the Artisan done this modification, the frozen fruits so obtained would still have been inferior to those obtained by applicants process based on the comparative examples in applicants specification.

Applicants respectfully submit that the Examiner has used the knowledge gained from applicants' disclosure as a blueprint in an attempt to reconstruct their claimed invention from isolated pieces of prior art. This approach contravenes the statutory mandate of §103 which requires judging obviousness at the point in time when the invention was made. *Grain Processing v. American Maize-Prod. Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988).

Claims 1, 4-5 and 13-14 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamane et al (EP0,815,746 – Yamane '746) in view of Yamane (JP 05-161449 – Yamane '449).

Statement of Facts

Yamane '746 has been discussed.

Yamane '449 is directed to a process "To preserve freshness of fruit and vegetable for a long period of time and to precool fruit and vegetable by sealing fruits and vegetables in a

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plastic bag, cooling approximately to the freezing point of fruit and vegetable, chilling close to a supercooling break temperature and gradually raising temperature approximately to room temperature." Abstract

Yamane '449 teaches that "Fruits and vegetables (e.g. spinach) are sealed in a plastic bag such as polyethylene having 20-100 μ thickness, cooled (primary cooling) to a temperature 1 to 2°C higher than the freezing point of fruit and vegetable in 1-12 hours, chilled at -5°C/1 hour to -0.5°C /24 hour to just higher [than the] supercooling break temperature (secondary cooling), allowed to stand as it is for 30 minutes to 1 year, heated (primary heating) up to 0°C, warmed (secondary heating) up to 5°C and finally heated (final heating) up to 10-20°C so that cooling and heating treatment are mildly carried out by stages, amounts of respiration and metabolism are maintained low to give storable and transportable fruits and vegetables having freshness for a long period of time." Abstract

Thus, the process taught in Yamane '449 does not involve the actual freezing of fruits, i.e., the fruits are heated before the supercooling break temperature is reached, i.e., before ice nucleation and growth.

Both the Yamane references are silent about the criteria that the cooling rate in the undercooling zone is selected such that the temperature difference between the surface and core of the fruit is less than 1.5°C

Applicants' argument

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The Examiner asserted that it a person of ordinary skill in the art would have been motivated to replace the cooling rate of Yamane '746 by the higher cooling rate recited in Yamane '449 because of the benefits taught by Yamane '449 in slowing down metabolic processes in foods and to therefore maintain the freshness of cooled fruits.

Both Yamane references are directed to a method for preserving perishable foods, including slowing down metabolic rate and have the same inventor.

Yamane '449 predates Yamane '746.

Yamane '449 is in point of fact not directed to freezing foods but rather preservation without freezing.

Although Yamane '449 discloses a cooling rate of $-5^{\circ}\text{C}/1\text{ hour}$ to $-0.5^{\circ}\text{C}/24\text{ hour}$ in the abstract, all the examples taught by Yamane '449 employ a cooling rate of $-0.5^{\circ}\text{C}/24\text{hr}$ or $-0.02^{\circ}\text{C}/\text{hr}$ which is precisely within the limits for the rate of cooling taught as essential by Yamane '746, i.e., $0.01\text{--}0.5\text{ }^{\circ}\text{C}/\text{hour}$.

Given the above facts scenario, applicants submit that a person of ordinary skill in the art reading both references in their entirety would not have been motivated to replace the cooling range taught by Yamane '746 by the cooling rate range disclosed by Yamane '449 and would have actually been dissuaded from doing so.

Since: i) both references disclose the same benefits; ii) both references are by the same inventor; iii) the later reference ('746) discloses a narrower range than the former ('449) which

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actually encompasses the cooling rates used in all the working examples of '449; applicants submit that the skilled artisan would have reasonably concluded that Yamane '746 taught the more optimal cooling conditions to achieve the stated benefits of slowing down metabolic processes in foods and maintaining freshness.

Consequently, applicants respectfully submit that the Examiner has again used the knowledge gained from applicants' disclosure as a blueprint in an attempt to reconstruct their claimed invention from isolated pieces of prior art. This approach contravenes the statutory mandate of §103 which requires judging obviousness at the point in time when the invention was made through the eyes of a person of ordinary skill in the art.

In view of the forgoing amendment and remarks, applicants respectfully request the 103(a) rejections be reconsidered and withdrawn and that the application be allowed to issue.

If a telephone conversation would be of assistance in advancing prosecution of the subject application, applicants' undersigned agent invites the Examiner to telephone him at the number provided.

Respectfully submitted,



Michael P. Aronson
Michael P. Aronson
Registration No. 50, 372
Agent for Applicant(s)

MPA/sm
(201) 894-2412